



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service *55024d*

Food and Drug Administration  
5100 Paint Branch Pkwy, HFS-607  
College Park, Maryland 20740

OCT 22 2004

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Nature's Sunshine Products  
75 East 1700 South  
Provo, UT 84606

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.naturessunshine.com> and has concluded that claims on this web site cause your products "Carbo Grabbers®" and "Fat Grabbers®" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of Carbo Grabbers® and Fat Grabbers® bears structure/function claims, including the following:

**Carbo Grabbers®:**

- "[B]lock the digestion of dietary starches with all-natural Carbo Grabbers."
- "It naturally and safely prevents the digestion of starchy carbohydrates and reduces the available calories your body may otherwise convert to fat."
- "Carbo Grabbers helps prevent weight gain from carbohydrate (starch) intake. Because carbohydrate breakdown is mostly blocked, undigested starches are carried into the intestinal tract where the body can eliminate them."
- "[S]tudies have shown that the equivalent of 2 capsules of this white bean extract [contained in Carbo Grabbers] effectively blocks 50 percent of the carbohydrates in a meal."

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- "Another study showed a 10lb. /month weight loss without any change in diet or exercise."
- "Helps Reduce Conversion of Carbohydrates to Calories"
- [H]elp reduce the amount of carbohydrates (starches, pasta, breads, etc.) which are converted to calories."

**Fat Grabbers®:**

- "Fat Grabbers® [Weight Loss] is an ideal product for anyone wanting to absorb less fat..."
- "Fat Grabbers ... traps fat molecules inside the intestinal tract before they can get into the bloodstream."
- "Fat Grabbers combines [components of] guar gum and psyllium hulls with chickweed and lecithin.... Research on guar gum and psyllium hulls indicates their effectiveness in minimizing the absorption of fat. Lecithin is a nutrient that works to break down fat, making it easier for the fibers to trap it. Chickweed contains saponins that also act as fat emulsifiers."
- "Fat Grabbers provide nutrients to help...absorb less dietary fat...."
- "Grabs Fat from the Food You Eat."
- "Decreases Fat through Elimination."
- "Fat Grabbers utilizes specific fibers to trap fat molecules. The trapped fat molecules are then unavailable for digestion and are eliminated through the Intestinal System."
- "Guar gum and psyllium have a natural trapping action with fat."
- "Chickweed and lecithin emulsify fat, allowing a more efficient way to reduce the amount of fat available to the body."

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your products to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

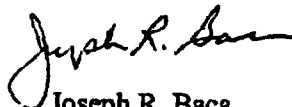
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You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for Carbo Grabbers or Fat Grabbers are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with a large initial "J" and a stylized "B".

Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety and Applied Nutrition